Remarks:

Claims 1 and 4-28 are pending in the application. In the Office action dated March 26, 2008, claims 1 and 4-28 were rejected under 35 U.S.C. § 103. Responsive to the Office action, Applicants request reconsideration of the Final Rejection in view of the following remarks.

Rejections under 35 USC § 103

Claims 1, 4, 5, 8-15, and 21-28 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Cox et al. (U.S. 6,234,167) in view of Poole (U.S. 6,158,431).

The Examiner suggests that it would have been obvious to one of ordinary skill in the art at the time of the invention to have used a correction factor as used in the device of Cox et al. as taught by Poole in order to produce the desired performance characteristic in a given environment. Applicants respectfully disagree.

Applicants note that claim 1 is directed to a medicament dispenser, where the medicament dispenser includes:

a) a medicament supply;

b) an ejector having a performance characteristic, the ejector being in fluid communication with the medicament supply;

c) an accumulator in fluid communication with the ejector;

d) a sensor configured to sense medicament pressure within the accumulator;

e) a valve intermediate the medicament supply and the accumulator, the valve configured to open and close in response to a sensed medicament pressure within the accumulator to regulate medicament pressure at the ejector;

and

f) a controller configured to actuate the ejector using an operational parameter to produce a plurality of medicament drops having target drop characteristics, the operational parameter including a correction factor based on the performance characteristic of the ejector.

The Examiner asserts that Cox et al. disclose an inhaler having a medicament supply (37), an ejector (29, 33), and accumulator (tube 27), and a valve intermediate the medicament supply and the accumulator. The inhaler of Cox et al. is shown below:

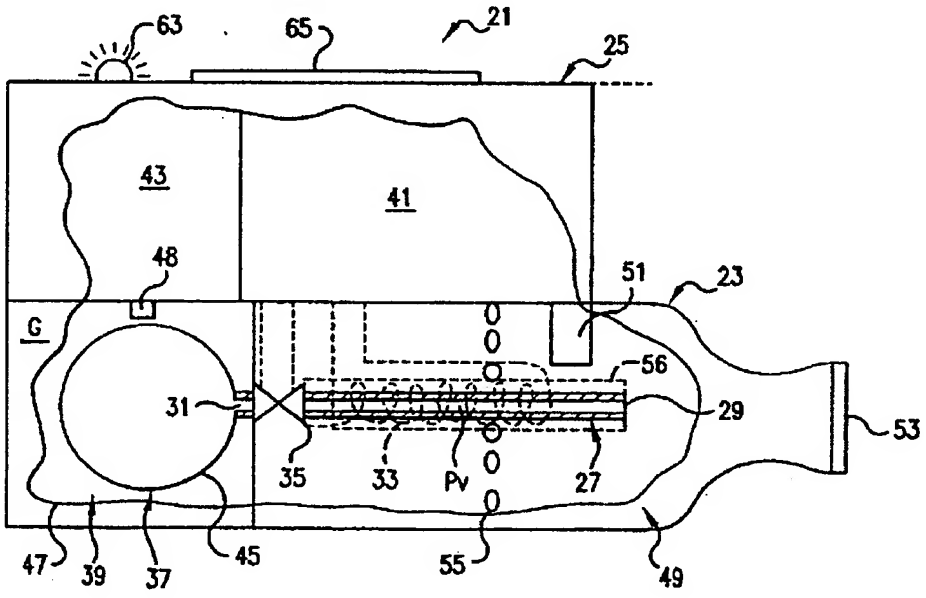

FIG.1

The Cox inhaler operates as follows: The source of material to be delivered **37** includes a flexible container **45**, and a pressurized chamber **47** in which the flexible container is disposed. Pressurized gas G is sealed in chamber **47** and surrounds flexible container **45**.

When it is desired to dispense material, activation of the inhaler results in valve **35** being opened, and power being supplied to heater **33** causing it to heat up to its desired operating temperature. The pressure of the gas G compresses the flexible container **45**, causing material to enter the tube **27** through the second end **31** of the tube in communication with the source of material. The material in the open-ended tube **27** is heated to a vaporization temperature in the tube by heater **33**, volatilizes, and then expands out of the free end **29** of the tube (see col. 4, lines 25 to col. 5, line 26).

The Examiner asserts that the inhaler of Cox includes all the elements of the claimed medicament dispenser. Specifically, the Examiner asserts that the Cox inhaler includes a medicament supply (**37**), an ejector (**29, 33**), an accumulator (tube **27**) in fluid communication with the ejector and a valve (**35**) intermediate the medicament supply and the accumulator. The Examiner clarifies this reasoning by stating that tube **27** is considered to be an accumulator as it is defined by the instant specification on page 3, as a volume in fluid communication with the ejectors. Applicants respectfully suggest that the Examiner is misapplying the Cox et al. reference, as well as misconstruing the plain meaning of the claims.

The recited medicament dispenser includes an accumulator in fluid communication with the ejector, and a sensor configured to sense medicament pressure within the accumulator. The Examiner points to col. 4, lines 25-30, which states that:

> "General operation of the aerosol generator **21** involves a user providing a signal, such as by compressing a button or performing some other action such as inhaling near the first end **29** of the tube **27** to actuate a flow sensing detector or a pressure drop sensing detector, which is received by the control device **43**."

The triggering device for the inhaler of Cox et al. may be a push button, a flow sensor, or a pressure drop sensor. Furthermore, the triggering device is not specifically depicted by Cox et al. in any way. Applicants suggest that a generic signaling device, having no particular location, and no specifically required function, fails to correspond to the "sensor configured to sense medicament pressure within the accumulator" as recited in claim 1. Anticipation under 35 U.S.C. § 102 requires that the identical invention be shown in as complete detail as is contained in the claim, and the elements arranged as required by the claim (see MPEP § 2131).

The recited medicament dispenser includes "a valve intermediate the medicament supply and the accumulator, the valve configured to open and close in response to a sensed medicament pressure within the accumulator to regulate medicament pressure at the ejector." The Examiner asserts that valve **35** is disposed between the medicament supply **37** and the "accumulator" tube **27**. Applicants suggest that the Examiner is misreading both the Cox et al. reference and the Applicants' claim.

The sensor of the claimed dispenser is functionally defined as being capable of regulating medicament pressure within the accumulator, and therefore at the ejector. Such regulation is accomplished by sensing the pressure within the accumulator and opening the valve between the medicament supply and the accumulator in order to regulate the pressure in the accumulator. This functionality is clearly set out in the plain language of claim 1.

The hypothetical sensor relied upon by the Examiner in rejecting claim 1 may be configured to register the push of a button, or a flow, or a drop in pressure, and is not required to be a pressure sensor. Furthermore, the Cox et al. reference fails to clearly teach or suggest where the sensor is located, and as such, it is submitted that it is unclear that the sensor could even theoretically function as the Examiner has suggested. However, these considerations are moot, because tube 27 of the Cox et al. inhaler of Cox et al. can never correspond to the accumulator of claim 1, because tube 27 is open-ended.

Claim 1 recites that the accumulator is in fluid communication with the ejector, that a sensor is configured to sense medicament pressure within the accumulator, and that a valve is intermediate the medicament supply and the accumulator, with that valve configured to open and close in response to a sensed medicament pressure within the accumulator to regulate medicament pressure at the ejector. Since tube **27** is open-ended, the pressure within the tube will always be ambient pressure. Any attempt to increase the pressure in tube **27** by opening valve **35** will result in a rapid depletion of the source material as all the medication escapes from open end **29** of tube **27**.

Furthermore, as set out in the Applicants' specification, the principle function of the accumulator is to regulate pressure at the ejector through the addition of additional material from the medicament supply, optionally enhanced by the presence of a compliant member (see page 5, lines 15-25). Aside from the functional requirements of the language of claim 1 itself, given the teaching of the specification, it is submitted that it is clear that the inhaler of Cox et al. does not include an accumulator, as recited in claim 1.

The dispenser of claim 1 further includes a controller configured to actuate the ejector using an operational parameter to produce a plurality of medicament drops having target drop characteristics, the operational parameter including a correction factor based on the performance characteristic of the ejector.

However, the Cox et al. inhaler fails to disclose the production of medicament drops. Cox et al. discloses that liquid material is forced into tube **27** by the pressure applied to source material **37**, where the material is "heated to a vaporization temperature in the tube, volatilizes, and expands out of the free first end of the tube" (col. 4, lines 40-43). The material goes directly from liquid to a heated gas and leaves tube **27** in that form. It is only when the volatilized material contacts cooler air that the material condenses to form an aerosol. The Examiner asserts that open end **29** and heater **33** correspond to the ejector of claim 1, but in this instance and according to the Cox et al. disclosure itself, the open tube of Cox et al. cannot be the ejector because it necessarily fails to produce a plurality of medicament drops, as recited in claim 1.

The Examiner has noted that the Poole reference was "cited merely as evidence that it is well known that determining volume from droplet diameter in an inhaler is well known in the art" (see the Office action at page 6, lines 4-6). Therefore, every other element of claim 1 must necessarily be found in the Cox et al. reference. For at least the reasons discussed above, the Cox et al. reference fails to disclose each and every element of claim 1. Therefore the Cox et al. reference, alone or in combination with Poole, fails to establish the *prima facie* obviousness of the dispenser of claim 1. As claims 4, 5, and 8-13 depend from claim 1, Applicants suggest that they are similarly not rendered obvious by the cited references.

Independent claim 14 recites an inhaler that includes:

a) a medicament supply;

b) a medicament accumulator in fluid communication with the medicament supply;

c) a compliant member fluidically coupled to the medicament accumulator;

d) a valve intermediate the medicament supply and the medicament accumulator;

e) a sensor configured to sense a medicament pressure within the medicament accumulator;

f) an ejector in fluid communication with the medicament accumulator, wherein the ejector has a performance characteristic; and

g) a controller configured to apply a correction factor to an operational parameter of the ejector, wherein the correction factor is determined by the performance characteristic of the ejector.

Applicants suggest that the Cox et al. and Poole references fail to establish the *prima facie* obviousness of the inhaler of claim 14 for at least the reasons that Cox et al. fails to disclose a medicament accumulator, as recited in claim 14; fails to disclose a "sensor configured to sense medicament pressure within the accumulator" as recited in claim 14; and fails to disclose a compliant member fluidically coupled to the medicament accumulator, as recited in claim 14, and as discussed above.

Independent claim 15 recites a method for calibrating a medicament inhaler to a target output characteristic, where the medicament inhaler has a medicament supply, a medicament accumulator in fluid communication with the medicament supply, a sensor configured to sense medicament pressure within the accumulator, a valve intermediate the medicament supply and the medicament accumulator, a medicament ejector in fluid communication with the medicament accumulator, and a controller configured to open and close the valve in response to a sensed medicament pressure within the accumulator.

For at least the reasons that the Cox et al. reference fails to disclose an inhaler having an accumulator, a sensor configured to sense medicament pressure within the accumulator, or a controller configured to open and close the valve in response to a sensed medicament pressure within the accumulator, Applicants suggest that the Cox et al. and Poole references fail to establish the *prima facie* obviousness of the method

of claim 15. As claims 21-27 depend from claim 15, Applicants also suggest they are similarly not rendered obvious by the cited references.

Independent claim 28 recites an inhaler that includes:

a) a means for supplying fluid medicament;

b) a means for ejecting fluid medicament, the means having a performance characteristic;

c) a means for accumulating fluid medicament in fluid communication with the ejector means;

d) a means for sensing fluid medicament pressure within the accumulator means;

e) a means for regulating an addition of medicament to the accumulator means from the fluid medicament supply means in response to the pressure sensing means; and

f) a means for actuating the ejector means using an operational parameter calculated from the performance characteristic of the ejector means.

Applicants suggest that the Cox et al. and Poole references fail to establish the *prima facie* obviousness of the inhaler of claim 28 for at least the reasons that Cox et al. fails to disclose "a means for accumulating fluid medicament in fluid communication with the ejector means", as recited in claim 28; fails to disclose "a means for sensing fluid medicament pressure within the accumulator means" as recited in claim 28; and fails to disclose "a means for regulating an addition of medicament to the accumulator means

from the fluid medicament supply means in response to the pressure sensing means" as recited in claim 28, and as discussed above.

For at least these reasons Applicants suggest that the Cox et al. and Poole references fail to establish the *prima facie* obviousness of the inhaler of claim 28.

Applicants suggest that the Examiner has failed to establish the *prima facie* obviousness of the rejected claims, and respectfully request the withdrawal of the rejection of claims 1, 4, 5, 8-15 and 21-28 under 35 U.S.C. § 103.

Claims 6, 7 and 16-20 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Poole (U.S. 6,158,431), as applied to claims 1-5, 8-15, and 21-28, and further in view of Poole et al. (U.S. 5,278,626).

As discussed above, Applicants suggest that the Cox et al. and Poole references fail to disclose each and every element of the rejected claims. Applicants additionally suggest that the Poole et al. reference similarly fails to disclose each and every element of the rejected claims, and also fails to supply the deficiency of Poole.

Applicants therefore assert that none of the cited references, either singly or considered in combination, disclose each and every element of the rejected claims. For at least these reasons, Applicants assert that the Examiner has failed to establish the *prima facie* obviousness of claims 6, 7 and 16-20, and they respectfully request the withdrawal of the rejection of the claims under 35 U.S.C. § 103.

Applicants believe that in view of the above amendments and remarks, this application is now in condition for allowance. Accordingly, Applicants respectfully request that the Examiner issue a Notice of Allowability covering the pending claims. If the Examiner has any questions, or if a telephone interview would in any way advance prosecution of the application, please contact the undersigned attorney of record.

Respectfully submitted,

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CERTIFICATE OF FACSIMILE TRANSMISSION

I hereby certify that this correspondence is being facsimile transmitted to Examiner K. Matter, Group Art Unit 3771, Assistant Commissioner for Patents, at facsimile number (571) 273-8300 on May 20, 2008.

Christie A. Doolittle